



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration
College Park, Maryland

MODIFIED WARNING LETTER

SEP 24 2003

Mr. George Economy
Chief Manager
Pride of Main Street Dairy LLC
214 Main Street South
Sauk Centre, Minnesota 56378

Dear Mr. Economy:

This Warning Letter supercedes our Warning Letter addressed to Helios Nutrition LTD dated September 9, 2003. The Food and Drug Administration (FDA) has reviewed the labels on your ½ gallon containers of PRIDE OF MAIN STREET "Milk," "2% Reduced Fat Milk," "1% Low Fat Milk," "Skim Milk" and "Chocolate Skim Milk." An FDA Investigator collected these labels during an inspection at your firm conducted on June 30, 2003.

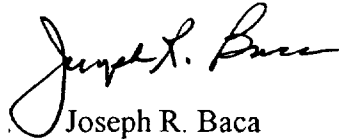
Our review reveals that these products are misbranded within the meaning of Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act). Under Section 403(a)(1) of the Act, a product is misbranded if its labeling is false in any particular. The labels of these products contain the statement "No Hormones," which is false. This statement is false because naturally occurring hormones are present in all milk and milk products. Due to the presence of naturally occurring hormones, milk cannot be produced in a way that renders it free of hormones. Therefore, milk and milk products cannot be labeled in a manner that falsely indicates that hormones are not present in the product.

The above violation is not meant to be an all-inclusive list of deficiencies on your labels. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct this violation and to prevent its future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please respond in writing, within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you have taken to correct the noted violation. Copies of the revised labels for the referenced products should be submitted with your response. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your response should be directed to David R. Yost, Director of Compliance, U.S. Food and Drug Administration, 3rd Ave. South, Minneapolis, Minnesota 55401. If you have any questions regarding any issue in this letter, please contact Tyra Wisecup, Compliance Officer, at 612-758-7114.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joseph R. Baca". The signature is fluid and cursive, with a large initial "J" and a stylized "B".

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition